
Efficacy and Safety of a New Treatment Modality: The ClearLight™ PhotoClearing System

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Summary Provided by Lumenis

SUMMARY: A narrow-band high intensity blue-violet light source, ClearLight™ PhotoClearing system has been successfully used for the treatment of mild to moderate inflammatory acne lesions in 150 subjects treated twice-weekly for four weeks. The average number of lesions per subject decreased from 20.3 at baseline to 5.3 after eight

treatments and 3.8 at one month after the last treatment. Overall, 63% of subjects had at least 70% clearing of their lesions and 20% of subjects experienced complete clearing of their inflamed lesions. The treatment was well tolerated, with only minimal side effects and only slight skin warmth felt by some patients during therapy.

INTRODUCTION

ACNE IS ONE OF THE MOST COMMONLY TREATED diseases in dermatology, occurring in up to 80% of people at some stage of life.¹ In spite of the multiple treatments available, many patients fail to improve adequately and may develop significant side effects.²

Acne usually occurs during adolescence and affects particular areas of the body, such as the face, chest, and back. It involves an excessive production of sebum by hypertrophic sebaceous glands. When these factors are accompanied by a defect in keratinization, the skin becomes a fertile ground for build-up of corneal clogs in the follicular infundibulum. These may remain aseptic or result in the growth of microorganisms (mainly *Propionibacterium acnes*) which are responsible for the inflammatory lesions (papules, pustules, nodules, and cysts) that often result in macules and permanent scars.

Acne is of considerable aesthetic significance and may cause mental stress in affected subjects. Although acne usually heals spontaneously in early adulthood, treatment measures can shorten the course, reduce the severity of the disease, and help to prevent complications. In many patients a combination of treatments aimed at correcting abnormal keratinization and reducing the proliferation of *Propionibacterium*, or *P. acnes*, is sufficient to control the disease.⁴

Sun exposure and a few artificial light sources have shown to have beneficial effects for acne, although until recently it was not clear which wavelengths of light contributed this favorable effect.³ Noncoherent visible light is thought to be a better photo activating light source for the treatment of acne than laser light because of its cost-effectiveness, uniform illumination, and time-efficiency in treating large areas.⁵ Topical aminolevulinic acid plus red light is a treatment for acne causing an apparent decrease in follicular bacteria, but it is associated with significant side effects such as phototoxicity to sebaceous follicles, considerable pain during treatment, perifollicular hyperpigmentation and prolonged suppression of sebaceous gland function.⁷

Phototherapy for acne is based on the fact that *P. acnes* produces porphyrins as part of its normal metabolism.⁸ Exposure of these compounds to specific wavelengths starts a chemical reaction that produce peroxide, which in turn kills the bacteria. *In vitro* tests of the visible light spectrum have shown that the strongest reaction occurs in the presence of narrow band, intense blue-violet light in the 405-420 nm wavelength range.⁹ This paper reports on the effectiveness of the ClearLight system, which emits blue-violet light for the treatment of acne lesions for subjects with a variety of skin types.

STUDY DESIGN

Subjects

This prospective study included 150 male and female subjects, 11 years of age or older, with Fitzpatrick skin types I to IV, representing all possible types and localizations of inflammatory acne vulgaris. Subjects had not received any acne treatment for one month prior to the start of the study and were in good health. Pregnant or nursing females, subjects with abnormal skin sensitivity or photosensitive skin, and subjects under treatment with systemic drugs were excluded.

Procedures

At the baseline evaluation, subjects provided informed consent and their clinical history was recorded. Treatments were applied to both sides of the body. Treatments consisted of eight 15-minute sessions (twice-weekly for four weeks) of exposure to narrow-band high intensity light. The light source (ClearLight, Lumenis.) was a metal halide lamp specially designed to emit homogeneous narrow band illumination at a wavelength range of 405-420 nm. At a distance of 25 cm from the light source, this resulted in a skin surface fluence of a minimum of 55 mW/cm² over an area of 20 x 20 cm². The treatments were followed by three follow-up visits over a two-month period. Inflammatory lesions (papules, pustules, nodules, or cysts) were counted and recorded at baseline and at each treatment follow-up visit. Subjects used a mild liquid soap (1% salicylic acid), a hydrating non-medicated gel twice daily and SPF 30 sun block once daily during the entire study period.

RESULTS

Subjects were between 11 and 49 years old, with an average age of 23.2 years. The majority of subjects (62%) had Fitzpatrick skin type III. The average number of lesions per site was similar for most subjects (Figure 2).

Efficacy

The average number of acne lesions per subject decreased significantly from 26.5 at baseline to 5.3 after eight treatments. One month after the end of treatment, the average number of lesions per subject decreased to 3.8, and remained at similar low levels at two months after the final treatment.

A total of 126 subjects (84.0%) completed the eight treatments and three follow-up visits. Among those who completed treatment and follow-up, subjects with lighter skin (type II) tended to have a faster response than subjects with darker skin (type III or IV), although there was no significant difference in the number of lesions per site at the end of treatment (Figure 2).

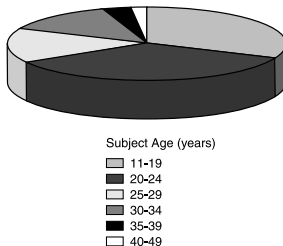


Figure 1: Subject Characteristics

Percentage of Lesions Cleared & Accumulated

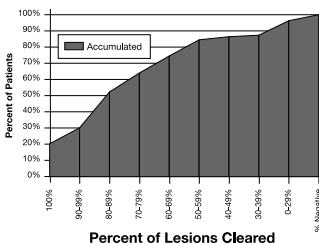


Figure 2: Percentage of Lesions Cleared and Accumulated on Complete Treatment and Follow-Up Cases

Overall, 20.2% of subjects who completed the study had 100% clearing of their lesions, 63.4% had at least 70% clearing of lesions, and 84.5% had at least 50% clearing. Only 11.6% of subjects who completed treatment showed no significant change (less than 30% improvement) in the number of lesions.

Safety

Treatment with this high intensity light source was well tolerated and accepted by the subjects, who reported only mild skin warmth during light exposure. The only side effects noted were mild erythema and scaling between the 2nd and 6th treatments, which has been hypothesized to be due to bacterial destruction and the inflammatory process rather than an effect of the light itself.

DISCUSSION

Twice-weekly treatments with a high-intensity, narrow band blue-violet light source (ClearLight) is an excellent treatment for inflamed acne skin lesions. The average number of lesions per subject decreased significantly from 26.5 at baseline to 5.3 after eight treatments and remained low two months after the end of treatment.

Acne lesions not infected with *P. acnes* do not respond to light therapy. Light treatment is only effective for acne lesions infected with *P. acnes*, since other acne-associated bacteria do not produce endogenous porphyrins. Approximately 10% of acne lesions are not caused by *P. acnes*. This compares favorably with the 11.6% of subjects in this study who showed no response to ClearLight treatment.

The ClearLight PhotoClearing system's, high intensity, narrow band blue-violet light appears powerful enough to affect both the skin surface and the ducts where *P. acnes* bacteria are highly concentrated.⁹ We believe that the twice-weekly treatment schedule resulted in a higher bacterial destruction rate than production rate and thus provided a faster and more effective response than antibiotic treatment.¹⁰ Additionally, light treatment avoids the possibility of acquiring antibiotic resistance, which has been observed with long-term antibiotic treatment of acne.¹⁰ However, there were no significant differences between skin types for the number of lesions at the end of treatment. All side effects observed were minor and of short duration.

In other subjects treated with the ClearLight, we have found that treatment efficacy and side effects vary with light exposure and energy levels. Treatment is most effective with durations between 12 and 15 minutes using at least 55 mW/cm² irradiance. These conditions provide the greatest efficacy for treating acne lesions with the fewest side effects.

It is difficult to predict ahead of time which subjects will respond. Light treatment is not effective for acne caused by bacteria other than *P. acnes* and bacterial isolation from acne lesions is neither easy nor precise. Porphyrins produced by *P. acnes* exhibit an orange-red fluorescence under Wood's Light (365 nm UVA light), which can be measured by digital fluorescence photography (DFP).¹¹ Further studies are planned to use this method to assess the effectiveness of the treatment and as a pre-exam to determine which cases of acne have high levels of porphyrins and may respond best to intense light treatment.

CONCLUSION

Treatment with this new narrow band, high intensity blue-violet light source (ClearLight) is safe and effective and may be the best single therapy available for the treatment of inflammatory acne lesions.

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